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FUJI CHEMICAL INDUSTRY

Pharmaceutical Technical Newsletter

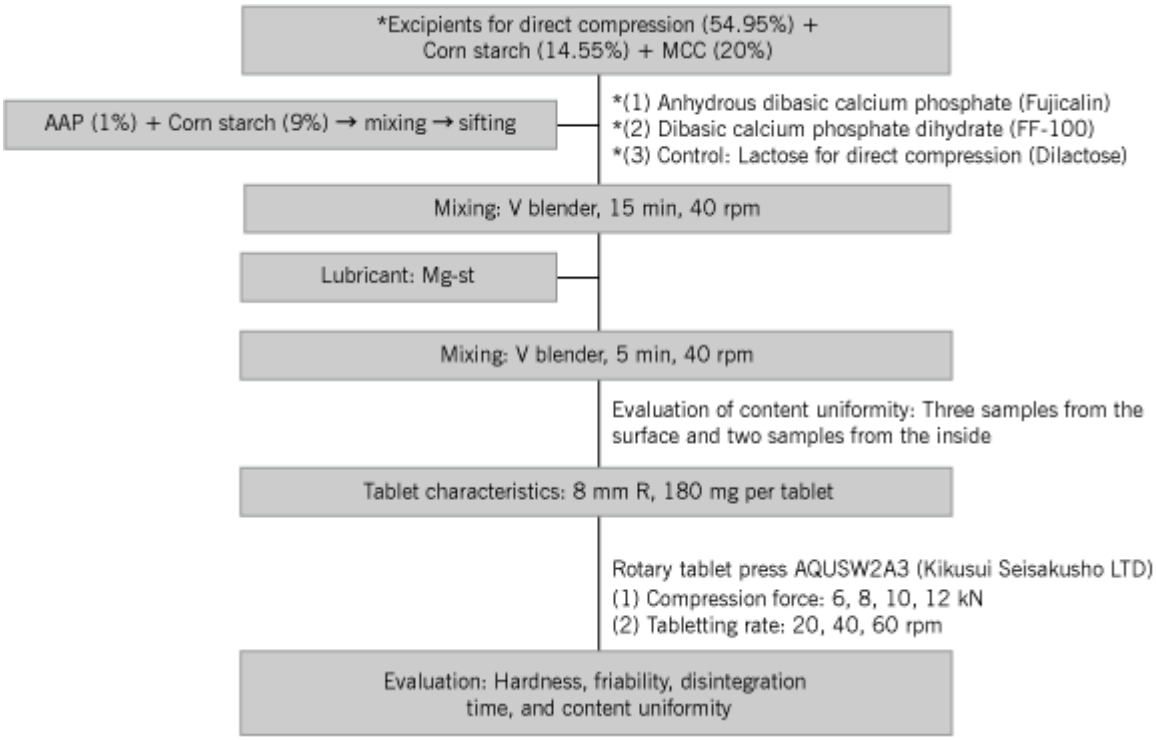
Comparison of tabletting properties of Fujicalin® with other similar direct compression excipients

Greetings!

Welcome. This issue of Fuji's newsletter presents preparation of acetaminophen tablets with Fujicalin and comparison with other similar direct compression excipients.

Direct compression (DC) is the preferred choice to manufacture tablets because it eliminates several steps involved in traditional wet granulation. When formulating DC tablets, the choice of excipient is very critical. The main attributes of a good DC excipient are excellent compressibility, good flowability and particle size distribution that ensures uniform blend. In this newsletter, we compare the tabletting properties of Fujicalin (DCPA),with Dilactose (granulated lactose) and DCPD in formulating acetaminophen (AAP) DC tablets. (Ref: M. Hasegawa, Proceedings of the Standard Formulation Research Association, 2007)

DC Schematic flow:

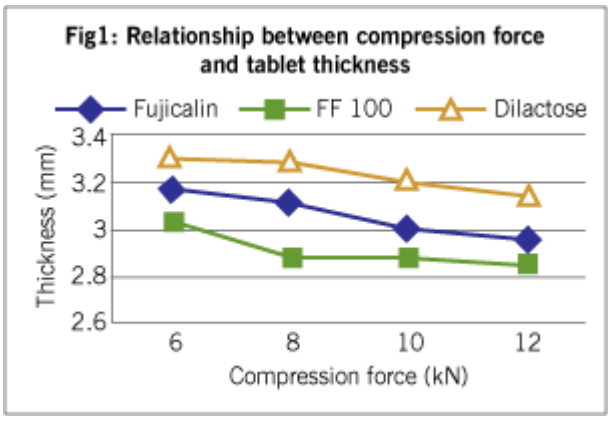


Physical properties of excipients :

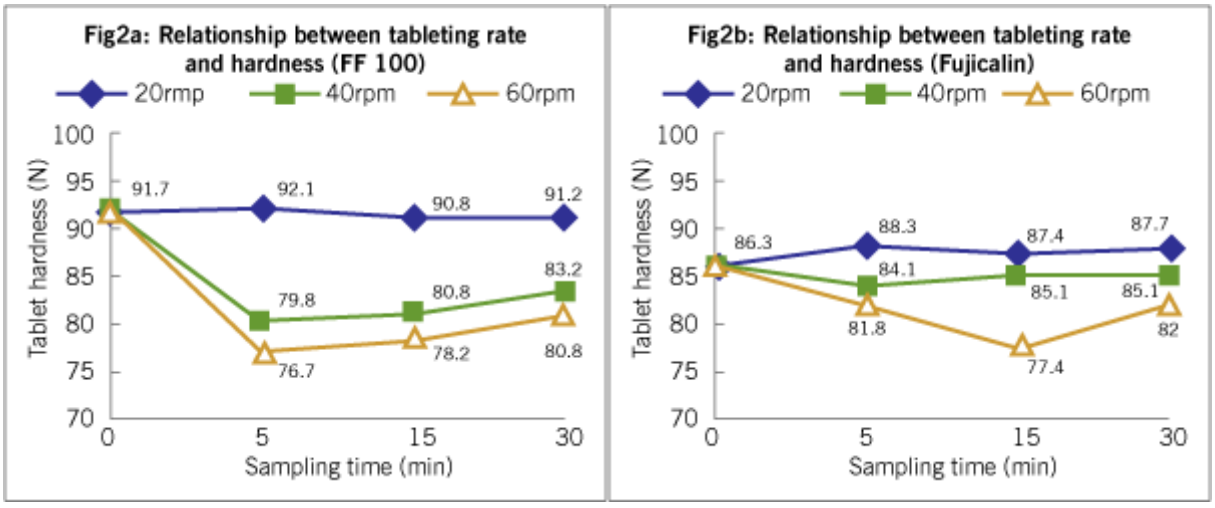
Excipient	Angle of repose (°)	Loose bulk density (g/mL)	Tapped bulk density (g/mL)	Compressibility (%)
Fujicalin	38	0.50	0.63	21.3
FF-100	38	0.63	0.88	27.9
Dilactose	39	0.50	0.75	33.4

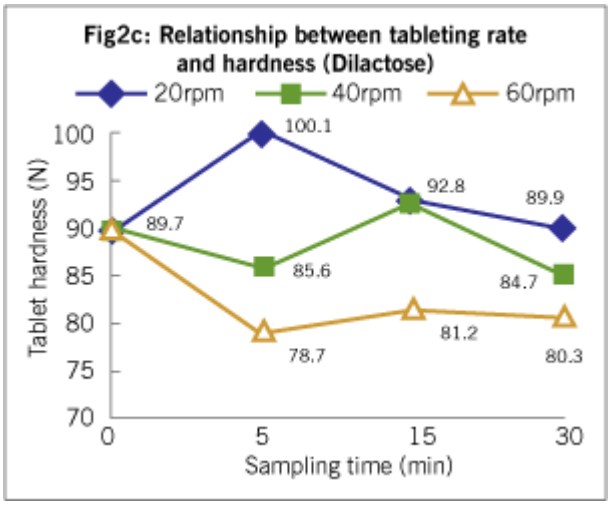
Results:

Tablet hardness increased with increased compression force with all three excipients. Fujicalin showed a comparatively higher hardness at all compression forces tested. However, DCPD (FF 100) produced the thinnest tablets followed by Fujicalin and Dilactose (Fig 1).



Tablet hardness at a constant compression force of 10 kN and different tabletting rates were measured by sampling tablets at different time intervals. Fujicalin showed the least variation with increased tablet rate (Fig 2a,b,c). At high tabletting rates, DCPD tended to show variation in tablet weight.





Content uniformity after blending was better when a triturated mixture (AAP 1% + cornstarch 9%) was prepared prior to blending with DC excipients. Friability was less than 0.25% for all three DC excipients tested.

Summary:

Tablet properties	Fujicalin	FF 100	Dilactose
Compressibility	+++	++	+
Hardness	+++	++	++
Compact thin tablets	++	+++	+
Tablet hardness at different tabletting rate	+++	+	+
Maintain tablet weight at different rate	+++	+	++
Content uniformity	+++	+++	+++
Friability	+++	+++	+++

(+++); Excellent (++); Fair (+) Poor

Conclusion:

Although Fujicalin, FF-100 and Dilactose have similar flow properties and behavior, Fujicalin showed less variation for the different characteristics tested resulting in high quality tablets.

Dosage and Safety:

Fujicalin is manufactured under strict quality control at our FDA-GMP certified facilities. Dibasic calcium phosphate anhydrous is widely used in oral pharmaceutical products and food products. It is generally regarded as relatively nontoxic and nonirritant material.

Fujicalin:

Chemical formula : $CaHPO_4$
Chemical Abstract Service (CAS) Number: 7757-93-9
U.S. Patent No. 5,486,365, Jan 1996
U.S. Drug Master File (DMF) filed, Conforms to USP/NF, EP and JP; and listed as GRAS

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Fuji Chemical Industry Co., Ltd. | 55 Yokohoonji Kamiichi Nakaniikawa-gun | Toyama | 930-0397 | Japan